

UNITED STATES PATENT AND TRADEMARK OFFICE

14

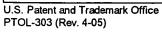
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P. Do. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
08/07/2001	Kanji Takada	P21010	2415
590 08/02/2005		EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C.		GHALI, ISIS A D	
1950 ROLAND CLARKE PLACE RESTON, VA 20191		ART UNIT	PAPER NUMBER
		1615	
	590 08/02/2005 M & BERNSTEIN, P D CLARKE PLACE	590 08/02/2005 M & BERNSTEIN, P.L.C. D CLARKE PLACE	590 08/02/2005 EXAM M & BERNSTEIN, P.L.C. GHALI, I O CLARKE PLACE 20191 ART UNIT

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)		
Advisory Action Before the Filing of an Appeal Brief	09/831,901	TAKADA, KANJI		
	Examiner	Art Unit		
	Isis Ghali	1615		
The MAILING DATE of this communication appe	ars on the cover sheet with the c	correspondence address		
THE REPLY FILED 21 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.				
1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:				
 a)				
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).				
Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL				
2. The Notice of Appeal was filed on A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). AMENDMENTS				
 The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or 				
(d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: (See 37 CFR 1.116 and 41.33(a)).				
 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): rejection of claim 8 under 112 first paragraph, new matter. 6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 				
7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed:				
Claim(s) objected to: Claim(s) rejected: Claim(s) withdrawn from consideration:				
AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, by because applicant failed to provide a showing of good an and was not earlier presented. See 37 CFR 1.116(e).	ut before or on the date of filing a N d sufficient reasons why the affida	Notice of Appeal will <u>not</u> be entered wit or other evidence is necessary		
9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to conshowing a good and sufficient reasons why it is necessary.	overcome <u>all</u> rejections under appe y and was not earlier presented. S	al and/or appellant fails to provide a See 37 CFR 41.33(d)(1).		
 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: 				
 see continuation sheet. 12. Note the attached Information Disclosure Statement(s). 13. Other: 	(PTO/SB/08 or PTO-1449) Paper	No(s)		



Claims 1-8, 10-18, 20-25 remain rejected as failed to comply with enablement requirement because with careful review to the specification, applicant did not disclose how the drugs will stay in the middle layer of the laminate without release till it reaches selected sites of the intestine. It is not clear from the disclosure how would the drug be prevented from release from the laminate because it can leach out from the uncovered sides from drug-containing layer. There is no showing that the formulation passes through the stomach and adheres to the intestine without release of the active agent or adherence to the stomach. Applicant shows that it can be inserted surgically in the intestine to release active agent in there, but not administered orally and still does not release the active agent or adhere to the mucosa before it reaches the intestine. The enteric polymers are pH sensitive and dissolve in acidic medium; thus, they can dissolve in the stomach and release the active agent before it reaches the target. It seems, from the present disclosure, that applicant manipulates other factors such as the thickness of the layer to control the site of the release and by encapsulating the laminate. Therefore, the claims are broad and do not meet the enablement requirements

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600